

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

*In re: Nexium (Esomeprazole Magnesium)
Antitrust Litigation*

This Document Relates to All Actions

MDL No. 2409

Civil Action No. 1:12-md-02409-WGY

**MEMORANDUM IN SUPPORT OF TEVA'S AND ASTRAZENECA'S
MOTION FOR JUDGMENT ON THE PLEADINGS**

Laurence A. Schoen, BBO # 633002
Adam L. Sisitsky, BBO # 637532
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKYAND POPEO, P.C.
One Financial Center
Boston, MA 02111
Telephone: (617) 542-6000
Facsimile: (617) 542-2241
LASchoen@mintz.com

KIRKLAND & ELLIS LLP
Jay P. Lefkowitz, P.C. (*pro hac vice*)
Karen N. Walker, P.C. (*pro hac vice*)
Kathryn L. Einspanier (*pro hac vice*)
655 Fifteenth Street, N.W., Suite 1200
Washington, D.C. 20005
Telephone: (202) 879-5000
Facsimile: (202) 879-5200
karen.walker@kirkland.com

*Attorneys for Teva Pharmaceuticals USA, Inc.
and Teva Pharmaceutical Industries, Ltd.*

[additional counsel on signature page]

TABLE OF CONTENTS

	Page
INTRODUCTION	1
BACKGROUND	5
A. The Hatch-Waxman Act Provides the First-Filer with 180 Days Exclusivity	5
B. Paragraph IV Litigation History	7
C. Ranbaxy's Well-Documented Regulatory Problems Prevented Entry Prior to May 27, 2014	8
D. Ranbaxy Still Has Not Obtained Final Approval Even After May 27, 2014.....	8
LEGAL STANDARD.....	9
ARGUMENT	10
I. Plaintiffs' Trigger Theory Is Foreclosed By Ranbaxy's Inability To Launch Prior To May 2014.....	12
II. Plaintiffs' Selective Waiver Theory Is Foreclosed Because Final FDA Approval Is Required In Order For An Applicant To Selectively Waive Its Exclusivity.....	13
III. Plaintiffs' Forfeiture Theory Is Foreclosed Because This Court Rejected Plaintiffs' Speculative Causation Theory That Alternative Milestones Would Have Been Negotiated Between Ranbaxy and FDA.....	14
IV. Any Other Theories Plaintiffs May Try To Revive Must Fail.....	15
CONCLUSION.....	17

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Boehringer Ingelheim Corp. v. Shalala</i> , 993 F. Supp. 1 (D.D.C. 1997).....	3, 6
<i>Bristol-Myers Squibb Co. v. Copley Pharm., Inc.</i> , 144 F. Supp. 2d 21 (D. Mass. 2000)	13
<i>City of Pittsburg v. W. Penn Power Co.</i> , 147 F.3d 256 (3d Cir. 1998).....	16
<i>Conley v. Gibson</i> , 555 U.S. 41 (1957).....	10
<i>HSBC Realty Credit Corp. (USA) v. O'Neill</i> , 745 F.3d 564 (1st Cir. 2014).....	9
<i>In re Metoprolol Succinate Direct Purchaser Antitrust Litig.</i> , Civil Action Nos. No. 06-52 (GMS), 06-71 (GMS), 2010 WL 1485328 (D. Del. Apr. 13, 2010)	7
<i>Indium Corp. of Am. v. Semi-Alloys, Inc.</i> , 781 F.2d 879 (Fed. Cir. 1985).....	13
<i>Jung v. Assn. of Am. Med. Colls.</i> , 184 Fed. Appx. 9 (D.C. Cir. 2006)	10
<i>Matsushita Elec. Indus. Co. v. Zenith Radio Corp.</i> , 475 U.S. 574 (1986).....	12
<i>Meijer, Inc. v. Biovail Corp.</i> , 533 F.3d 857 (D.C. Cir. 2008).....	12
<i>Mova Pharm. Corp. v. Shalala</i> , 140 F.3d 1060 (D.C. Cir. 1998).....	6, 13
<i>Perez-Acevedo v. Rivero-Cubano</i> , 520 F.3d 26 (1st Cir. 2008).....	10
<i>Portugues-Santana v. Rekomdiv Int'l Inc.</i> , 725 F.3d 17 (1st Cir. 2013).....	9
<i>R.G. Fin. Corp. v. Vergara-Nunez</i> , 446 F.3d 178 (1st Cir. 2006).....	9

TABLE OF AUTHORITIES (CONT'D)

	Page(s)
<i>RSA Media, Inc. v. AK Media Grp., Inc.</i> , 260 F.3d 10 (1st Cir. 2001).....	12, 13
<i>Simmons v. Galvin</i> , 575 F.3d 24 (1st Cir. 2009).....	10
<i>United States v. Ranbaxy Labs., Ltd.</i> , No. 1:12-cv-00250-JFM (D. Md. Jan. 26, 2012)	9
<i>Verizon Commc'n's Inc. v. Law Offices of Curtis V. Trinko, LLP</i> , 540 U.S. 398 (2004).....	3, 13
<i>Whitmore v. Arkansas</i> , 495 U.S. 149 (1990).....	16
Statutes	
21 U.S.C. § 355.....	passim
35 U.S.C. § 271.....	5
Other Authorities	
Wright & Miller, 5B Federal Practice and Procedure: Civil 3d § 1357 (Supp. 2007)	9
Rules	
Fed. R. Civ. P. 12(c)	9
Regulations	
64 Fed. Reg. 42,873 (Aug. 6, 1999).....	6, 13, 16
67 Fed. Reg. 66,593 (Nov. 1, 2002).....	6

INTRODUCTION

Teva and AstraZeneca respectfully move for judgment on the pleadings under Fed. R. Civ. P. 12(c) based on this Court’s causation rulings (on Ranbaxy’s and AstraZeneca’s summary judgment motions and plaintiffs’ motions for reconsideration).¹ In those rulings, this Court held that plaintiffs are “unable to support” an argument that Ranbaxy could have entered the market with generic Nexium earlier than May 27, 2014, the licensed-entry date under its settlement agreement with AstraZeneca due to Ranbaxy’s “continuing, and well-documented difficulties with obtaining FDA approval.” Feb. 12, 2014 Order (ECF No. 857) (“Order”) at 5-6.

This indisputable fact blows a gaping hole in plaintiffs’ case regarding the Teva Nexium settlement. Ranbaxy was the first generic manufacturer to file an ANDA for generic Nexium, and the Hatch-Waxman Act barred FDA from granting final approval to Teva until 180 days *after* Ranbaxy launched. 21 U.S.C. § 355(j)(5)(B)(iv). Accordingly, even assuming—for the sake of this motion—that but for its settlement with AstraZeneca, Teva would have been willing and able to launch at risk *and* that Teva could have gotten *tentative* approval for its generic Nexium earlier in the but-for world, Teva *still* could not have entered the market prior to May 2014 because it could only enter *after* Ranbaxy, and it was not feasible for Ranbaxy to enter prior to May 2014. *See, e.g.*, Order at 6. In particular, this Court’s Order forecloses *any* of plaintiffs’ remaining scenarios by which they claim Teva could have entered prior to May 2014: (i) trigger by Ranbaxy; (ii) waiver of exclusivity; or (iii) forfeiture of exclusivity.

Plaintiffs claimed in their motions for reconsideration of the Court’s causation summary judgment rulings regarding Ranbaxy that plaintiffs’ “primary” theory is that the parties “would

¹ Teva and AstraZeneca intended to file this motion after receiving the Court’s opinion fully explicating its summary judgment rulings, which the Court indicated would be forthcoming in “early August” so as to conform this motion to the detailed findings of the Court. However, given that the trial is now only six weeks away, we bring this dispositive motion now in order to ensure the Court may consider it prior to the scheduled trial date.

have settled" (based on a "payment free settlement") for a May 2012 launch date. *See* Feb. 28, 2014 Pls.' Mot. for Recons. (ECF No. 871) at 3.² But Ranbaxy could not have launched then. Thus, under the Hatch-Waxman Act, there are only three possible ways Teva could have entered before May 2014.³ Those are:

- Scenario I—Teva launches 180 days after Ranbaxy launches;
- Scenario II—Teva launches after Ranbaxy waives exclusivity;
- Scenario III—Teva launches after Ranbaxy involuntarily forfeits exclusivity.

All three are *foreclosed* by the Court's Order and precluded as a matter of law. Under the Hatch-Waxman Act, the paths by which Teva could have obtained final FDA approval and launched generic Nexium prior to May 27, 2014 are limited. Plaintiffs' remaining three scenarios—2012 entry based on Ranbaxy's exclusivity being (i) triggered, (ii) waived, or (iii) involuntarily forfeited—are completely foreclosed by this Court's findings, which are law of the case. *First*, Teva could not have launched after expiration of Ranbaxy's 180-day exclusivity because this Court held that Ranbaxy could not have entered prior to May 2014. Order at 6 ("Plaintiffs are unable to support an argument that earlier generic entry would have been feasible

² In their motions for reconsideration, plaintiffs expressly disclaimed that they were asking the Court "to reconsider whether the evidence supports a jury finding that Ranbaxy would have entered the Nexium market 'at risk.'" Pls.' Mot. for Recons. at 4. They claimed that "was never our primary theory." *Id.* Instead, they limited their motions to their primary theory—"that a payment free settlement would have led to an earlier date for licensed (agreed upon) entry." *Id.* at 4-5. They went on to describe their "primary causation theory" as involving a "scenario in which a payment-free agreement yields an earlier licensed entry date (around May of 2012)." *Id.* at 5. Accordingly, the only scenarios remaining are plaintiffs' 2012 entry scenarios (summarized in the report of their expert, Cheryl Blume, as Scenarios 3a, 3b and 3c).

³ Plaintiffs originally posited—through their expert—eight supposed scenarios under which earlier generic entry could have occurred. *See* Aug. 23, 2013 Blume Report ("Blume Rpt.") at 10-13. The first three scenarios assumed no settlements were reached and Ranbaxy (alone or collaborating with Teva) would have launched "at risk" in the 2008-09 timeframe, with either a Ranbaxy launch (1a), a selective waiver (1b), or a voluntary relinquishment (1c). All three scenarios are precluded since plaintiffs moved to reconsider only based on a 2012 licensed entry date. The second set of (two) scenarios posited similar "a" and "b" alternatives assuming a December 2010 licensed entry date, also now abandoned in favor of a 2012 theory. The third scenarios posit plaintiffs' primary, current, and remaining theory—of a May 2012 licensed entry date. Scenario 3a assumes a Ranbaxy launch, 3b assumes a selective waiver, and 3c assumes an *involuntary* forfeiture (as Blume concedes a voluntary forfeiture after 2010 would be implausible, *id.* at 51). *Id.* at 12-13.

due to Ranbaxy's continuing, and well-documented difficulties with obtaining FDA approval"). If Ranbaxy was unable to launch prior to May 2014, it could not (as a matter of law) have triggered its exclusivity period so as to allow Teva to launch 180 days later. (Part I.)

Second, Ranbaxy could not have selectively waived to Teva, because final FDA approval is required in order to selectively waive to another company, and this Court has already ruled that Ranbaxy would not have received final approval by May 27, 2014. *Id.* Without obtaining final FDA approval *and* commercially launching the product, Ranbaxy could not (as a matter of law) selectively waive its exclusivity to Teva prior to May 27, 2014. *See Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1 (D.D.C. 1997). Accordingly, Teva could not have launched any generic product prior to May 27, 2014 based on a selective waiver theory. (Part II.)⁴

Third, the Court rejected plaintiffs' arguments that Ranbaxy could have negotiated earlier milestone dates with FDA—the only alleged basis for plaintiffs' claim that Ranbaxy would have involuntarily relinquished its exclusivity by failing to meet those earlier dates. The Court found no causation notwithstanding plaintiffs' arguments that Ranbaxy and FDA might have negotiated different dates. *See* Order at 6; Jan. 9, 2014 Pls.' Opp'n to Ranbaxy Mot. Summ. J. on Causation (ECF No. 791) ("Pls.' Ranbaxy Opp'n") at 15-17. This Court's rulings thus dispensed with plaintiffs' theory that FDA would have been willing to allow Ranbaxy to enter the market with Nexium any earlier than May 2014 or to issue earlier deadlines in the Consent Decree. *Id.* Therefore, plaintiffs' theory that Ranbaxy would have done so, would then have failed to meet

⁴ In addition, even if selective waiver were possible—which it is not—no antitrust claim may be based on a theory that parties should have been expected to cooperate or enter business together. *See Verizon Commc'n's Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

those dates and forfeited, and that Teva would have entered once such dates were negotiated and missed, resulting in Ranbaxy's involuntary forfeiture, cannot stand. (Part III.)⁵

The Court's earlier Order finding plaintiffs' causation theories regarding Ranbaxy's ability to enter prior to May 2014 to be defective has only been bolstered by the passage of time. Ranbaxy's licensed entry date passed on May 27, 2014 and Ranbaxy has still not entered the market with generic Nexium (on its own or with any other manufacturer)—clear evidence that Ranbaxy's regulatory problems with its ANDA—and not Ranbaxy's or Teva's patent settlements—are what prevented not just Ranbaxy's entry but Teva's too. Plaintiffs' complaint is not with Teva but with the exclusivity provisions of the Hatch-Waxman Act itself. Thus, plaintiffs' causation theories fail—not just as to Ranbaxy but as to Teva as well.

In sum, plaintiffs cannot show that AstraZeneca's settlement with Teva *caused* Teva's delayed market entry. Based on this Court's finding that Ranbaxy was unable to enter prior to May 27, 2014, Teva would not have been able to enter any earlier than its licensed-entry date. Even though Teva now has a license to enter, Teva remains blocked to this day, not because of its settlement with AstraZeneca, but because it cannot get FDA approval. Even if Teva had obtained tentative approval by now (which it has not), it would still be unable to lawfully launch. Accordingly, Teva and AstraZeneca are entitled to judgment on the pleadings on all claims arising from the Teva settlement because, like Ranbaxy, Teva could not have entered the market with generic Nexium earlier than May 27, 2014.

⁵ Nor could plaintiffs assert any voluntary relinquishment theory given that they now posit a 2012 licensed-entry causation theory and concede voluntary relinquishment after 2010 would not have been plausible. *See* Blume Rpt. at 51. Finally, although plaintiffs have abandoned the theory that Teva would have entered prior to May 2014 by winning all phases of its patent challenge, there would be no evidence to support such a claim should they try to revive it. Their own expert fails to address this scenario in any analysis. *Id.* at 10-14. There also is no evidence to show that Teva could have triggered Ranbaxy's exclusivity period by winning non-appealable final judgments as to every patent at issue in Teva's Paragraph IV litigation and declaratory judgment action *and launched* before May 2014. (Part IV.)

BACKGROUND

A. The Hatch-Waxman Act Provides the First-Filer with 180 Days Exclusivity.

The 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (the Act), created section 505(j) of the Act, which established the abbreviated new drug application (ANDA) approval process. That process allows generic versions of previously approved innovator drugs to be approved and brought to market without undergoing new clinical safety studies.

An ANDA applicant must include one of four patent certifications (I through IV) for each patent listed by the innovator that claims the drug or a method of use in the *Approved Drug Products with Therapeutic Equivalence Evaluations* or *Orange Book* claiming a drug. By filing a Paragraph IV certification, the ANDA applicant contends that such patent is invalid or will not be infringed by the manufacture, use, or sale of its generic drug product. 21 U.S.C. § 355(b)(2)(A). The Paragraph IV certification is an artificial act of infringement, allowing the patent owner to file patent litigation even though the generic product has not been sold on the market yet. 35 U.S.C. § 271(e)(2)(A).

The Hatch-Waxman Act incentivizes patent challenges and promotes generic competition by rewarding the first generic company to file a Paragraph IV ANDA (“first-filer”) with a 180-day period of exclusive marketing, as an economic incentive for bearing the risk and expense of a patent challenge. 21 U.S.C. § 355(j)(5)(B)(iv). Significantly, no other generic can obtain final FDA approval to enter the market until the first-filer’s 180-day exclusivity period has either run out or been forfeited. *See id.* The 180-day exclusivity period does not begin running until the first-filer commences commercial marketing of the generic drug product. *Id.*

There are two ways in which a first-filer can *voluntarily* choose to waive or forfeit its exclusivity period. *First*, under certain circumstances, a first-filer may selectively waive its

exclusivity in favor of another ANDA or ANDAs containing a Paragraph IV certification. *See Boehringer Ingelheim Corp.*, 993 F. Supp. at 1-3 (selective waiver). In order to selectively waive, however, the first-filer must first *trigger* its exclusivity period by obtaining *final* FDA approval *and* commercially marketing the drug. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1070 (D.C. Cir. 1998) (exclusivity period runs from first commercial marketing); *see also* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, at 42,881 (Aug. 6, 1999), *withdrawn on other grounds* by 67 Fed. Reg. 66,593 (Nov. 1, 2002) (“[A]n applicant may selectively waive its exclusivity only after the 180-day exclusivity period has begun to run . . .”).

Second, a first-filer may relinquish its exclusivity altogether. In contrast to selective waiver, relinquishment cannot be done in favor of any one company, so no company has any statutory exclusivity in the event of such a relinquishment. *See* 64 Fed. Reg. at 42,881 (contrasting selective waiver and relinquishment). Unlike selective waiver, a first-filer may relinquish whether or not it has triggered its exclusivity and does not need to obtain final approval to take this step. *Id.* at 42,881.

If, however, a first-filer does not voluntarily waive or forfeit its exclusivity period, a subsequent filer cannot enter unless it forces a triggering event (which, if successful, can lead in some circumstances to the forfeiture of the first-filer’s exclusivity period). To force a triggering event, a later filer must obtain final, non-appealable court decisions, typically from the Federal Circuit, finding that all patents which the first-filer challenged under Paragraph IV are invalid, unenforceable, or not infringed, and it must also have tentative approval for its own ANDA. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb); *see also* *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, Civil Action Nos. No. 06-52 (GMS), 06-71 (GMS), 2010 WL 1485328, at *2 (D. Del.

Apr. 13, 2010). Where (as here), the brand manufacturer does not initiate infringement litigation with respect to *each* of the challenged patents, the later generic filer must initiate a declaratory judgment action over the remaining patents. If and when the court in both lawsuits—in the patent litigation and the declaratory judgment action—issues “final decision[s] from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that [each] patent is invalid or not infringed,” the first-filer has 75 days to begin marketing its generic drug. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Only if the first-filer fails to market in those first 75 days will the first-filer forfeit its exclusivity, allowing later generic filers to enter the market. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Otherwise, later filers can only enter 180 days after the first-filer begins marketing.

B. Paragraph IV Litigation History

AstraZeneca holds fourteen patents related to Nexium. Feb. 21, 2013 Direct Purchaser Pls.’ Consol. Am. Compl. (ECF No. 131) (“Compl.”) ¶ 73.⁶ On October 14, 2005, Ranbaxy was the first to file a generic Nexium ANDA that included a Paragraph IV certification that its product would not infringe any valid claim of any listed Nexium patent that would expire after October 2007. Compl. ¶¶ 83, 117. In November 2005, within 45 days of receiving notice of Ranbaxy’s ANDA certification, AstraZeneca sued Ranbaxy, triggering the 30-month litigation stay under the Hatch-Waxman Act. Compl. ¶ 84. During the litigation, Ranbaxy received tentative approval of its ANDA from FDA on February 5, 2008. Compl. ¶¶ 10, 154. AstraZeneca and Ranbaxy reached a settlement, and the district court entered a corresponding consent judgment in April 2008. Compl. ¶ 117.

⁶ See also Feb. 1, 2013 End Payor Pls.’ Corrected Consol. Am. Compl. (ECF No. 114); Nov. 14, 2013 Walgreen Co. et al. Am. Compl. (ECF No. 515); Nov. 11, 2014 Rite Aid Corp. et al. Am. Compl. (ECF No. 516); Nov. 14, 2013 Giant Eagle, Inc. Am. Compl. (ECF No. 517); Apr. 11, 2014 CVS Pharm., Inc. Compl. (docketed in 1:14-cv-11788). Plaintiffs’ other complaints are substantively similar to direct purchaser plaintiffs’ complaint (ECF No. 131). Therefore, this memorandum refers to ECF No. 131 but incorporates plaintiffs’ other complaints.

On January 26, 2006, Teva notified AstraZeneca that it had filed ANDA 78-003 with a Paragraph IV certification for generic Nexium, and AstraZeneca initiated patent litigation against Teva in March of that year. Compl. ¶¶ 101-02. After Ranbaxy settled with AstraZeneca in April 2008, Teva filed a declaratory judgment action seeking to obtain a favorable judgment regarding all Orange Book-listed Nexium patents, including patents that were not asserted in AstraZeneca's infringement action. Compl. ¶ 123. After nearly four years of litigation, Teva and AstraZeneca settled in January 2010. Compl. ¶ 127.

C. Ranbaxy's Well-Documented Regulatory Problems Prevented Entry Prior to May 27, 2014.

On February 12, 2014, this Court held that "the Plaintiffs are unable to support an argument that earlier generic entry would have been feasible due to Ranbaxy's continuing, and well-documented difficulties with obtaining FDA approval." Order at 6. As a result, the Court concluded that plaintiffs cannot prove that Ranbaxy could have launched a generic Nexium product prior to May 2014. *Id.*

D. Ranbaxy Still Has Not Obtained Final Approval Even After May 27, 2014.

Due to the fact that it still lacks final approval, Order at 6, Ranbaxy *still* has not launched generic Nexium in the United States,⁷ even though its licensed-entry date under the settlement agreement with Astra Zeneca, May 27, 2014, has long since passed. Moreover, because Ranbaxy's Consent Decree with the FDA gives it until September 30, 2014 to reach certain

⁷ U.S. FDA, Drugs@FDA, Drug Approval Reports, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu> (selecting "Original Abbreviated New Drug Approvals (ANDAs) by Month"; no final approvals for esomeprazole magnesium from February 2014 through August 2014) (last visited Aug. 22, 2014).

milestones before it risks forfeiting its exclusivity,⁸ no generic manufacturer, including Teva, could launch generic Nexium before that date.

After Ranbaxy and Teva settled their Nexium patent litigations with AstraZeneca in April 2008 and January 2010, respectively, at least five other generic manufacturers (including DRL) settled their own patent suits with AstraZeneca—each for a licensed-entry date of May 27, 2014—yet not one of these generic manufacturers has even received tentative approval to launch generic Nexium, even though they have licenses to launch under their respective agreements with AstraZeneca.⁹ None can obtain final approval from FDA due to Ranbaxy’s exclusivity.

LEGAL STANDARD

Any party may move for judgment on the pleadings once they are closed. Fed. R. Civ. P. 12(c); *Portugues-Santana v. Rekomdiv Int’l Inc.*, 725 F.3d 17, 25 n.6 (1st Cir. 2013). “The court may supplement the facts contained in the pleadings by considering documents fairly incorporated therein and facts susceptible to judicial notice,” *R.G. Fin. Corp. v. Vergara-Nunez*, 446 F.3d 178, 182 (1st Cir. 2006); *Portugues-Santana*, 725 F.3d at 25 n.7, including matters of “public record, orders, [and] items appearing in the record of the case,” Wright & Miller, 5B Federal Practice and Procedure: Civil 3d § 1357 (Supp. 2007). A court may grant a motion for judgment on the pleadings when, considering those facts, the case can be decided as a matter of law. *R.G. Fin. Corp.*, 446 F.3d at 182; *HSBC Realty Credit Corp. (USA) v. O’Neill*, 745 F.3d 564, 570 (1st Cir. 2014). The Court cannot accept plaintiffs’ bald assertions, unwarranted inferences or speculation, or sweeping legal conclusions. *Perez-Acevedo v. Rivero-Cubano*, 520

⁸ Consent Decree at 14, *United States v. Ranbaxy Labs., Ltd.*, No. 1:12-cv-00250-JFM (D. Md. Jan. 26, 2012); Blume Rpt. at 23 (esomeprazole magnesium is “ANDA 4” and the “date certain” is September 30, 2014).

⁹ U.S. FDA, Drugs@FDA, Drug Approval Reports, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu> (reviewing “Tentative Approvals by Month,” showing no tentative approvals for esomeprazole magnesium other than Ranbaxy’s tentative approval in February 2008).

F.3d 26, 29 (1st Cir. 2008). Here, because plaintiffs can ““prove no set of facts in support of [their] claim which would entitle [them] to relief,”” dismissal with prejudice is proper. *Jung v. Assn. of Am. Med. Colls.*, 184 Fed. Appx. 9, 10 (D.C. Cir. 2006) (quoting *Conley v. Gibson*, 555 U.S. 41, 45-46, 78 (1957)); *see Simmons v. Galvin*, 575 F.3d 24, 30, 45 (1st Cir. 2009) (dismissing claim with prejudice and noting that questions of statutory interpretation are particularly appropriate for resolution under Rule 12(c)).

ARGUMENT

In its Ranbaxy causation rulings, this Court held there was no record evidence—only speculation—that Ranbaxy could have launched its generic Nexium product before May 27, 2014. *E.g.*, Order at 5-6. Based on these findings, judgment on the pleadings must also follow for Teva.

This Court previously held that genuine issues of material fact about “Teva’s readiness and intent to engage in an earlier generic launch” and whether “Teva deliberately slowed its Nexium ANDA process as a result of the Teva-AstraZeneca settlement agreement,” prevented summary judgment for Teva on the issue of causation. Order at 4. Teva and AstraZeneca do not challenge those rulings here. Instead, Defendants submit that *even if* Teva could have obtained tentative approval at an earlier date and *even if* it was willing and had the capacity to launch “at risk,” as a matter of law *it could not have launched* its generic Nexium prior to its licensed launch date of May 27, 2014 due to Ranbaxy’s statutory exclusivity and Ranbaxy’s inability—recognized by this Court—to obtain final FDA approval and launch prior to that date.

As a matter of law, because Ranbaxy was the first to file its generic Nexium ANDA, it received 180 days of exclusive marketing of generic Nexium. 21 U.S.C. § 355(j)(5)(B)(1). Teva, and all other generic manufacturers, were legally *barred* from launching their products until 180 days after Ranbaxy had launched and could not obtain final FDA approval. Thus,

based on the Court’s finding that Ranbaxy could not have launched prior to May 2014, all three of plaintiffs’ remaining 2012 licensed entry scenarios for Teva are barred: (I) the Ranbaxy launch trigger scenario, (II) the selective waiver scenario, and (III) the forfeiture scenario.

Trigger. As explained below, Teva could not have obtained *final* FDA approval and launched generic Nexium until 180 days after Ranbaxy launched, which this Court has squarely held would not have occurred prior to May 27, 2014. Order at 6. Therefore, the Teva-AstraZeneca agreement cannot have *caused* plaintiffs’ alleged injury and Teva is entitled to judgment as a matter of law. *See* Part I below.

Selective Waiver. Nor can plaintiffs’ selective waiver theory present a viable alternative scenario in light of this Court’s causation rulings. Plaintiffs’ selective waiver scenario cannot be a viable causation theory because a first-filer must have final FDA approval and have launched in order to selectively waive—and this Court has found there is no evidence Ranbaxy could have done so prior to May 27, 2014. Thus, Ranbaxy could not have selectively waived to Teva. *See* Part II below.

Forfeiture. Plaintiffs’ final remaining causation theory—*involuntary forfeiture*—is also precluded. The Court has already rejected plaintiffs’ argument that the FDA and Ranbaxy would have negotiated earlier deadlines in the Consent Decree. Order at 6. Therefore, the Court has already rejected plaintiffs’ *involuntary relinquishment* theory. *Id.*¹⁰ *See* Part III below.

¹⁰ In their motions for reconsideration, plaintiffs limited their causation theory to a 2012 licensed entry date, thus foreclosing any pre-2012 voluntary relinquishment theory. Moreover, plaintiffs appear to have abandoned their “Teva would have won” scenario—they state their “primary” theory is now a 2012 licensed entry date, their expert does *not* include Teva winning the patent litigation in any of her scenarios, and plaintiffs assert they will not attempt to litigate the outcome of the Teva patent cases. In any event, and out of abundance of caution, Teva explains in Part IV why there is no evidence to support any such scenarios. (*See* Part IV.)

I. Plaintiffs’ Trigger Theory Is Foreclosed By Ranbaxy’s Inability To Launch Prior To May 2014.

Plaintiffs’ first scenario for its April 2012 “licensed entry” date is that Ranbaxy would have entered at or shortly after that time, and that Teva would have entered 180 days later.¹¹ But it is now indisputable that Teva could not have entered 180 days after April 2012 because Ranbaxy could not have launched prior to May 2014. Order at 6 (“Plaintiffs are unable to support an argument that earlier generic entry would have been feasible due to Ranbaxy’s continuing, and well-documented difficulties with obtaining FDA approval”) Accordingly, Teva could not have obtained final FDA approval and launched two years earlier than its licensed date—in 2012—as plaintiffs (and their expert) posit absent relinquishment or an appellate victory in all of the underlying patent litigation. *See Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008).

Even if Teva had tentative approval in 2012 (which it did not), it could not launch until 180 days after Ranbaxy did, as plaintiffs’ own expert concedes. Blume Dep. at 165-66, 298 (Teva could not launch because “Ranbaxy’s exclusivity prevents Teva from getting final approval” and “Teva cannot launch a product until it has a final approval”). The Court has held that Ranbaxy’s well-documented regulatory hurdles caused the alleged delay in the launch of its generic Nexium (regardless of the settlement agreements), Order at 5-6, and it is clear that these regulatory hurdles, combined with Ranbaxy’s exclusivity period, would have also prevented Teva from launching its generic Nexium prior to May 27, 2014. Judgment is appropriate where plaintiffs cannot show that the alleged conspiracy *caused* plaintiffs any injury. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986); *RSA Media, Inc. v. AK Media Grp., Inc.*, 260 F.3d 10, 15 (1st Cir. 2001). A manufacturer’s failure to enter the market

¹¹ See Blume Rpt. at 12-13.

does not cause antitrust injury unless the manufacturer was “ready, willing, *and able* to manufacture . . . during the relevant period.” *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 882 (Fed. Cir. 1985) (emphasis added). In particular, causation cannot be established where the first-filer’s marketing exclusivity period has not begun to run. *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23, 25 (D. Mass. 2000).¹²

II. Plaintiffs’ Selective Waiver Theory Is Foreclosed Because Final FDA Approval Is Required In Order For An Applicant To Selectively Waive Its Exclusivity.

Plaintiffs’ selective waiver theory is likewise no longer viable after the Court’s February 2014 Order. In order to selectively waive, the first-filer must first trigger its exclusivity period both by obtaining *final* approval *and* beginning to commercially market the drug. *See Mova Pharm. Corp.*, 140 F.3d at 1070 (180-day exclusivity period runs from first commercial marketing of the drug); *see also* 64 Fed. Reg. at 42,881 (“[A]n applicant may selectively waive its exclusivity only after the 180-day exclusivity period has begun to run”). Because the Court has held that there is no evidence to support the conclusion that Ranbaxy would have received final approval and launched generic Nexium prior to May 27, 2014, it is indisputable as a matter of law that Ranbaxy could not selectively waive to Teva (or anyone else) before that date. There is no basis for plaintiffs to argue to a jury that Ranbaxy would have selectively waived in favor of Teva under these circumstances.¹³

¹² None of Blume’s “A” scenarios are possible, even without plaintiff’s abandonment of the first two (pre-2012) theories. Scenarios 1a, 2a, and 3a all posit that Ranbaxy would have entered the market well before its May 2014 licensed-date and at least six months before Teva. Blume Rpt. at 10-14. Under the Court’s Opinion and Order, these entry scenarios are no longer in play because they all require an earlier launch date by Ranbaxy, which the Court rejected.

¹³ Even if a selective waiver would have been possible, an antitrust claim could not be based on a theory that competitors should have been required to do business together to avoid antitrust liability. *See, e.g., RSA Media, Inc.*, 260 F.3d at 15-16 & n.8; *Trinko*, 540 U.S. at 408.

III. Plaintiffs' Forfeiture Theory Is Foreclosed Because This Court Rejected Plaintiffs' Speculative Causation Theory That Alternative Milestones Would Have Been Negotiated Between Ranbaxy and FDA.

Teva and AstraZeneca are entitled to judgment on all claims arising from the Teva Nexium settlement because the Court has already rejected plaintiffs' third and final remaining scenario—that Ranbaxy would have negotiated earlier FDA consent decree dates permitting a 2012 launch when it granted Ranbaxy's causation motion. Order at 6. As a result, plaintiffs' far-fetched entry theory as to Teva—that Ranbaxy would have negotiated such dates, failed to meet them, and therefore involuntarily forfeited its exclusivity such that Teva could have obtained final approval earlier and launched—is also precluded.

Plaintiffs' involuntary relinquishment scenario rests on the same speculation this Court previously rejected—that Ranbaxy could have and would have negotiated earlier milestone deadlines in its Consent Decree with the FDA. In their opposition to Ranbaxy's motion for summary judgment, plaintiffs posited a but-for world where Ranbaxy had settled with AstraZeneca for an April 2012 licensed-entry date and negotiated an earlier August 2012 consent decree milestone date with the FDA. Order at 5-6; Pls.' Ranbaxy Opp'n at 15-19.¹⁴ In their opposition to Teva's motion for summary judgment, plaintiffs hypothesized that if Ranbaxy failed to meet this hypothetical milestone date under the hypothetical consent decree, and forfeited its 180-day exclusivity in August 2012, Teva would have obtained approval and entered. Jan. 9, 2014 Pls.' Opp'n to Teva's Mot. Summ. J. on Causation (ECF No. 789) ("Pls.' Teva Opp'n") at 8.¹⁵ But the Court has already rejected that. There is *no evidence* that FDA would have negotiated and held Ranbaxy to such early milestones or that FDA would have

¹⁴ See also Blume Rpt. at 12-13.

¹⁵ See also Blume Rpt. at 13.

forced a relinquishment of Ranbaxy's exclusivity in 2012, as this Court recognized in granting summary judgment on the issue of causation regarding Ranbaxy. Order at 5-6. In turn, any theory of 2012 entry by Teva premised on plaintiffs' hypothetical milestone negotiations between Ranbaxy and the FDA also fails.

IV. Any Other Theories Plaintiffs May Try To Revive Must Fail.

Plaintiffs should be limited to the only three scenarios that correspond to their 2012 "licensed entry" theory—the only theory upon which they moved for reconsideration. As such, any pre-2012 causation theories, voluntary relinquishment theories, or litigation success theories should be precluded.

First, all theories of pre-2012 entry have been expressly abandoned. Plaintiffs moved for reconsideration solely based on their "primary causation theory" which was that an agreed upon license would have permitted Ranbaxy to obtain final approval "on or before May 2012." *Id.* Plaintiffs insisted that their "but for" scenario was one "in which a payment-free agreement yields an earlier licensed entry date (around May of 2012)." *Id.*; *see also id.* at 19 ("plaintiffs' primary basis to overcome the patent hurdle to earlier generic Nexium entry is a payment-free agreement yielding an earlier agreed launch date around May of 2012"); Mar. 27, 2014 Pls.' Reply in Supp. Mot. to Recons. New Evidence (ECF No. 890) at 7 ("Ranbaxy would have entered into a *payment-free* settlement providing an earlier entry date (for example around 2012)"). Accordingly, any pre-2012 theories are foreclosed.

Second, although a "voluntary" relinquishment theory is not included in plaintiffs' 2012 "licensed entry" theory (scenarios 3a, 3b, and 3c)—and should therefore be ignored—it would be defective even if properly preserved. That is because it is legally impossible for a first-filer (such as Ranbaxy) to transfer its exclusivity to another applicant (such as Teva) through voluntary relinquishment. Such a relinquishment would not afford Teva with any legal

exclusivity, but would rather simply eliminate Ranbaxy's regulatory exclusivity altogether. 64 Fed. Reg. at 42,881. Under those circumstances, any generic manufacturer who had tentative approval and whose 30-month stay had expired could seek final approval from the FDA and launch their generic Nexium.¹⁶

Third, plaintiffs have expressly disclaimed any theory that Teva would have prevailed on all patent claims at trial and on appeal and thus triggered any exclusivity prior to May 2014, as well they should since such a theory is speculative as a matter of law. *See, e.g., Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."); *Copley Pharm., Inc.*, 144 F. Supp. 2d at 23 (citing *City of Pittsburg v. W. Penn Power Co.*, 147 F.3d 256, 268 (3d Cir. 1998) (assuming generic launch based on the likelihood of winning a patent lawsuit is nothing more than "speculation"). A litigation trigger could only occur if: (i) Teva *won* the Paragraph IV patent lawsuit brought by AstraZeneca, (ii) Teva won its declaratory judgment lawsuit against AstraZeneca, (iii) Teva *won* both lawsuits on appeal, (iv) Teva received tentative FDA approval, and (v) Ranbaxy failed to launch its generic Nexium within 75 days. Pls.' Teva Opp'n at 8-11. Tellingly, however, plaintiffs have never advanced this theory, it is omitted completely from Blume's scenarios, and none of plaintiffs' experts claim that Teva could have *won each and every* patent claim through appeal *and launched* before May 27, 2014. Instead, plaintiffs have recognized that settlement was the only realistic option, stating: "The plaintiffs' primary "but for" scenario is that AstraZeneca and Ranbaxy would have entered into a payment-free settlement—one without a reverse payment—thereby providing an earlier entry date (for

¹⁶ Even Dr. Blume admitted that this option would be attractive to Teva only *prior to June 2010*. Blume Rpt. at 11. After June 2010, "Teva would not likely pay Ranbaxy to relinquish its 180-day exclusivity, because Teva would have had insufficient assurance of 'de facto' exclusivity to make paying Ranbaxy for relinquishment a safe bet." *Id.* at 51. Accordingly, it is completely implausible under plaintiffs' 2012 licensed entry theory.

example around 2012).” Feb. 28, 2014 Pls.’ Mot. to Recons. New Evidence (ECF No. 868) at 10. Thus, given this Court’s findings, Teva and AstraZeneca are entitled to judgment as a matter of law on all claims arising from the Teva Nexium settlement.

CONCLUSION

Based on the Court’s ruling that Ranbaxy could not have launched its generic Nexium prior to its licensed-entry date of May 27, 2014, the Court should also grant Teva and AstraZeneca judgment on the pleadings with regard to their patent settlement.

Dated: August 25, 2014

Respectfully submitted,

/s/ Laurence A. Schoen

Laurence A. Schoen, BBO # 633002
Adam L. Sisitsky, BBO # 637532
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKYAND POPEO, P.C.
One Financial Center
Boston, MA 02111
Telephone: (617) 542-6000
Facsimile: (617) 542-2241
LASchoen@mintz.com
ALSisitsky@mintz.com

KIRKLAND & ELLIS LLP

Jay P. Lefkowitz, P.C. (*pro hac vice*)
Karen N. Walker, P.C. (*pro hac vice*)
Kathryn L. Einspanier (*pro hac vice*)
655 Fifteenth Street, N.W., Suite 1200
Washington, D.C. 20005
Telephone: (202) 879-5000
Facsimile: (202) 879-5200
karen.walker@kirkland.com
katie.einspanier@kirkland.com

*Attorneys for Teva Pharmaceuticals USA,
Inc. and Teva Pharmaceutical Industries,
Ltd.*

Dane H. Butswinkas (Of Counsel)
John Schmidlein (Of Counsel)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
Ph: (202) 434-5000
Fax: (202) 434-5029
DButswinkas@wc.com
JSchmidlein@wc.com

William A. Zucker, Esq., BBO # 541240
MCCARTER & ENGLISH, LLP
265 Franklin Street
Boston, MA 02110
Ph: 617-449-6500
Fax: 617-607-9200
wzucker@mccarter.com

Michael P. Kelly (*pro hac vice*)
MCCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
Ph: 302-984-6301
Fax: 302-984-2493
mkelly@mccarter.com

Counsel for AstraZeneca LP, AstraZeneca AB, and Atkiebolaget Hässle

CERTIFICATE OF SERVICE

I hereby certify that on the 25th day of August 2014, I filed and served the foregoing via the Court's CM/ECF system, which will serve notification of such filing by email to all counsel of record.

/s/ Laurence A. Schoen
Laurence A. Schoen